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LETTERS

ADVERSE EVENT REPORTING IN CLINICAL TRIALS

Adverse event reporting in surgical trials and early phase studies: the need for new and joint perspectives

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We support the consensus recommendations from Lineberry and colleagues for improving the credibility and transparency of the reporting of adverse events in publications of research sponsored by industry.¹

We also support a similar process for the development of standards and consensus for the reporting of benefit and harm outcomes in surgical trials, including early phase surgical studies. Recent reviews have summarised the heterogeneity of outcome reporting in many surgical areas,²⁻⁶ including in the evaluation of innovative surgical procedures.⁷ This limits evidence syntheses and increases the risk of outcome reporting bias. For early phase studies, the reporting of selective outcomes is likely to lead to overoptimistic assessment of new interventions and under-reporting of adverse effects.

Without systematic and transparent evaluation, as recommended by Lineberry and colleagues—for example, specifying the numerators and denominators for all events—surgeons continue to innovate without reliable information about adverse effects. This means that the true extent of harm to patients is uncertain and often only becomes apparent after national registries summarise outcomes.^{3 8} This uncertainty could be minimised by the routine measurement and reporting of adverse events in early phase surgical studies.

Surgeons must work with industry, the National Office for Clinical Research Infrastructure, and professional bodies to urgently develop minimal mandated sets of the benefit and harm outcomes to measure in each phase of surgical innovation. Methods developed with the COMET initiative (www.comet-initiative.org/) enable the identification and categorisation of benefit and harm outcomes in early phase surgical studies and

the development of minimal mandated sets of benefit and harm outcomes using consensus methods. Bristol University has received an NIHR Biomedical Research Centre award to develop such sets, with the potential to expedite the swift rejection of unsafe or ineffective techniques and promote the efficient development of promising innovations.

Competing interests: None declared.

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